a "detection space", which are unclear because the terms binding, amplification, and detection, are unclear. As Applicants understand the rejection, the Examiner appears to question whether the binding space, the amplification space and the detection spaces refer to a single chamber or vessel, or whether the vessels are separate from each other. The Examiner also of the opinion that the term "binding" is unclear because it is not clear whether the term refers to a nucleic acid collection space or a hybridization space for nucleic acids which would refer to a detection space. Applicants respectfully traverse.

The specification clearly explains the functions of the binding space, the amplification space and the detection space. Claim 36 itself explains that the binding space is for purifying nucleic acids by immobilizing the nucleic acids and separating impurities. This is further described in the specification, *e.g.*, page 4, first full paragraph, which provides:

> The nucleic acids are purified according to the invention in a binding space where the nucleic acids are immobilized and separated from impurities. The nucleic acids can for example be immobilized by covalent or adsorptive binding in the binding space. In addition, it is also possible to bind the nucleic acids by means of high affinity interactions such as sequence-specific binding using hybridization probes or binding partners of high affinity binding pairs such as avidin/biotin or specific antibodies.

Thus, the specification clearly describes the binding space. Further, the detection space is described in the specification, *e.g.*, page 8, first full paragraph:

> [T]he purified nucleic acids are amplified in an amplification space. Since according to the invention the amplification space contains at least part of the binding space, it is not necessary to transfer or transport the eluted nucleic acids and thus the associated losses in yield can be avoided.

Here, the specification explains that the amplification space can be the same as or at least should be a part of the binding space. Finally, the specification provides that the detection of the amplification product can be carried out by known methods in a detection space. Optionally, the detection space contains at least part of the amplification space and/or at least part of the binding space (*see e.g.*, page 9, second full paragraph). Thus, the specification clearly explains that the binding, amplification, and detection spaces may be separate or the same. Claim 36 requires that the amplification space comprise at least the part of the binding space. However, the detection space can be separate and distinct from the binding and application spaces. Also, it is clear that the binding space is used for nucleic acid collection which may include hybridization of the nucleic acids (*see e.g.*, page 4, first full paragraph). Thus, the binding space may hybridize nucleic acid both in purification and detection of nucleic acids.

Accordingly, as the terms "binding space," amplification space," and "detection space" are clearly described in the specification, Applicants respectfully request that the rejections of claims 36-41 pursuant to 35 USC § 112, second paragraph, be withdrawn.

Claim rejections under 35 USC § 102(b)

Claims 36-41 and 68 stand rejected under 35 USC § 102(b) as anticipated by Lipshutz, *et al*, U.S. Patent No. 5,856,174 (hereinafter "Lipshutz"). Lipshutz fails to anticipate independent claim 36 because Lipshutz does not teach step b of claim 36 wherein "an amplification space for amplifying nucleic acids comprising at least part of the binding space...." To the contrary, Lipshutz teaches:

> [A] plurality of distinct reaction chambers for carrying out sample acquisition, preparation and analysis operations. In particular, a sample to be analyzed is introduced into the device whereupon it will be delivered to one of several distinct reaction chambers which are designed for carrying out a variety of reactions as a prelude to analysis of the sample.

Column 4, lines 22-29, (emphasis added).

Examiner refers to the above quoted language in column 4, and column 7, line 65 through column 8, line 42, as teaching that the amplification space comprises at least part of the binding space. To the contrary, Lipshutz teaches that the reaction chambers are distinct. Nowhere does Lipshutz teach that the "amplification reaction chamber" (*see*, column 7, line 65 through column 8, line 42) is the same or part of an "extraction chamber." (*see*, column 5, lines 45-48) The extraction chamber is a "separate accessible chamber" *Id.*

Since Lipshutz fails to teach an amplification space that comprises at least part a binding space as in claim 36, Lipshutz does not anticipate claim 36. Since Lipshutz does not anticipate independent claim 36, it cannot anticipate dependent claims 37-41. Similary, Lipshutz provide no teaching of a capillary reaction vessel surrounded by a heatable metal layer, as in claim 68, wherein the layer is coated on the capillary reaction vessel. Accordingly, Applicants respectfully request that the rejection under 35 USC § 102(b) based upon Lipshutz be withdrawn.

Claims 36-41 and 68 stand rejection under 35 USC § 102(b) as anticipated by Haff, *et al*, U.S. Patent No. 5,827,480 (hereinafter "Haff"). According to the Examiner, Haff teaches a capillary PCR instrument or apparatus comprising a capillary reaction vessel surrounded by a heatable metal exchanger. The Examiner has not pointed to any disclosure in Haff which would be relevant to claim 36. Therefore, Applicants assume that Haff is cited which regard to claim 68 only.

As amended, claim 68 recites that the heatable metal layer is coated on the capillary reaction vessel. Haff fails to teach this limitation. For example, in Figure 12 and column 16, lines 1 through 8, Haff explains that the device comprises two metal block heat exchangers 170 and 172 separated by a layer of insulation 174. Thus, Haff fails to teach that the metal layer is coated on the capillary detection space. Since Haff fails to teach every element of claim 68, Haff fails to anticipate claim 68.

Accordingly, Applicants respectfully request that the rejection pursuant to 35 USC § 102(b) based upon Haff be withdrawn.

CONCLUSION

With the above amendments and remarks, Applicants respectfully submit that the application is in condition for allowance. If Examiner is of the opinion that a telephone conference with expedite prosecution of the application, Examiner is encouraged to contact Applicants' undersigned representative.

Respectfully submitted,

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APPENDIX A

Serial No.: 09/780,206
Inventor: Michael Fritz
Attorney Docket No.: 01-1096

Marked up version of amended claim to show changes made

68. (Amended) An apparatus for amplifying nucleic acids comprising a capillary reaction vessel surrounded by a heatable metal layer wherein the layer is coated on the capillary reaction vessel.

APPENDIX B

Serial No.: 09/780,206
Inventor: Michael Fritz
Attorney Docket No.: 01-1096

A clean copy of pending claims

36. An apparatus for detecting nucleic acids in a sample, comprising:

(a) a binding space for purifying the nucleic acids by immobilizing the nucleic acids and separating impurities,

(b) an amplification space for amplifying the nucleic acids comprising at least part of the binding space, and

(c) a detection space for detecting the nucleic acids.

37. The apparatus of claim 36 further comprising reagents for purifying, amplifying and detecting the nucleic acid.

38. The apparatus of claim 36, wherein the detection space comprises a part of at least one of the amplification space and the binding space.

39. The apparatus of claim 36, wherein at least one of the binding space and the amplification space comprises a capillary space.

40. The apparatus of claim 39 wherein the capillary space is a capillary reaction vessel surrounded by a heatable metal layer.

41. The apparatus of claim 39 wherein the capillary space is glass or polystyrene.

68. An apparatus for amplifying nucleic acids comprising a capillary reaction vessel surrounded by a heatable metal layer wherein the layer is coated on the capillary reaction vessel.